

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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THE PROCTER & GAMBLE COMPANY,	:
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Plaintiff,	:
	:
v.	:
	:
ULTREO, INC.,	:
	:
Defendant.	:
	:
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Civil Action No. 07-8379(RJS)

**DIRECT EXAMINATION
DECLARATION OF
LAWRENCE A. CRUM**

I, LAWRENCE A. CRUM, hereby declare under penalty of perjury as follows:

Background and Qualifications

1. I am a Research Professor of Electrical Engineering and Bioengineering at the University of Washington ("UW") and the Principal Physicist at the Center for Industrial and Medical Ultrasound at the Applied Physics Laboratory of UW.

2. The Center for Industrial and Medical Ultrasound (the "Ultrasound Center") is one of the pre-eminent academic ultrasound research facilities in the United States. The Ultrasound Center collaborates with the private sector to develop or improve the use of ultrasound technology for industrial, military and medical purposes.

3. The Ultrasound Center is at the forefront of exciting new ways to employ ultrasound, particularly in the health sciences. As a recent example, the Ultrasound Center is currently involved in the cutting-edge research and development of a method to use ultrasound waves to ablate malignant tumors in humans without the need for invasive surgery. Another example involves the use of ultrasound transmissions to break down kidney stones in the human body.

4. I have written or co-authored over 300 articles in the field of ultrasound

technology. I have edited several books on the subject. I have more than ten patents relating to ultrasound technology.

5. Over the past 35 years, I have been actively involved in more than 70 funded research projects involving ultrasound. I have been a member of the editorial board of several journals relating to ultrasonics, and a reviewer of numerous journals relating to ultrasonics, fluid mechanics and acoustics. I have lectured on these subjects at numerous professional institutes and symposia, and serve on a variety of committees or societies relating to ultrasound. Among the many different kinds of applications of ultrasound I have investigated, I have studied the use of ultrasound to clean dental surfaces in the mouth.

6. I have a Bachelor's of Science in Mathematics from Ohio University, as well as a Masters and Ph.D in Physics from that university.

7. A copy of my CV which discloses my various publications is annexed hereto as Exhibit A has been submitted to the Court as Defendant's Exhibits ("DX-71").¹ I have been retained previously as an expert on ultrasound in litigation as follows:

(7a), as an expert witness in a case involving a patent dispute between two competing inventors of ultrasound contrast agents,

(7b), as an expert witness in a case involving a patent dispute between two competing inventors of ultrasound liposuction devices, and

(7c), as an expert witness in a case involving a dispute between co-owners of a company concerning the use of ultrasound to clean semiconductor wafers.

8. I am being compensated for this matter at the rate of \$125/hour plus expenses.

¹ The exhibits that Ultreo intends to use at the hearing of P&G's motion for a preliminary injunction have been pre-marked as Defendant's Exhibits ("DX-__"). I understand that copies of these exhibits have been provided to the Court and to counsel for P&G.

Expert Opinions and Analysis

9. The ability of ultrasound waves — *i.e.*, inaudible waves of high frequency sound — to clean objects is well accepted in the scientific community and demonstrated in numerous “real world” applications. For many years, ultrasound has been used to clean jewelry, semi-conductors used for electronic circuitry and surgical instruments and even ship hulls. Ultrasound has also been used for years to remove plaque and tartar in human mouths using dental ultrasonic scalers.

10. Here is how the ultrasonic cleaning process generally works: An object such as jewelry is placed into a liquid medium that has entrained within the liquid small microbubbles. Ultrasound transmissions are induced into that medium. The ultrasound waves activate the microbubbles and cause them to pulsate (*i.e.*, to expand and contract), often to grow in size, and to oscillate energetically. These pulsating and oscillating bubbles can clean the surfaces of objects through a mechanical action that involves the displacement of the liquid surrounding the bubble, and by the creation of shear forces in the liquid through liquid microstreaming. These mechanical forces act on any particles or debris residing on the surface of an object, and often removing them from the surface.

11. I have thoroughly examined the Ultreo toothbrush. The ultrasound transducer in the Ultreo powered toothbrush generates acoustic waves at a frequency of 323 kilohertz (*i.e.*, 323,000 cycles per second). This is substantially in excess of the -30-40 kilohertz waves that are commonly used to clean jewelry. Ultreo’s ultrasound transducer has a 10% duty cycle. This means that it is generating acoustic pulses at the 323 kHz frequency for 1/10 of the time that the toothbrush is activated. During a two minute brushing, there are nearly 4 million cycles of ultrasound energy supplied by the Ultreo ($120 \text{ seconds} \times 323,000 \text{ cycles/second} \times 0.10 = 3,876,000 \text{ cycles}$). In my opinion, the Ultreo transducer produces a sufficient number of acoustic

cycles to effect cleaning.

12. I observed the Ultreo toothbrush perform in a laboratory experiment conducted at the Ultrasound Center with the participation of Dr. James Christopher McInnes of Ultreo. In this experiment, a glass slide coated with a biofilm of Streptococcus Mutans (S. Mutans), a common plaque bacteria, was placed in liquid medium of water and microbubbles. The slide was exposed to ultrasound treatment by the Ultreo toothbrush submerged in the liquid medium where the bristles did not contact the slide.

13. The Ultrasound Center has high speed photographic equipment that can visually record ultrasound cleaning, even at a microscopic level. Our staff filmed the laboratory experiment designed by Dr. McInnes and produced videos of the cleaning mechanism. Three videos (Movies Nos. 1, 2 & 3) are contained in a CD-rom disk which may be found at DX-72. I have reviewed these videos as well as still frames taken from the videos and can make several observations.

14. The ultrasound waveguide effectively channeled the ultrasound waves from the transducer to the liquid surrounding the transducer, as well as toward the tips of the toothbrush bristles. The intensity of the ultrasound generated by the transducer/waveguide combination was sufficient to activate the microbubbles in the liquid medium. Upon being activated, the bubbles began to oscillate energetically during the time interval that the ultrasound was engaged. These oscillating bubbles developed strong mechanical forces in the liquid and were observed to remove the plaque biofilm from the glass slide.

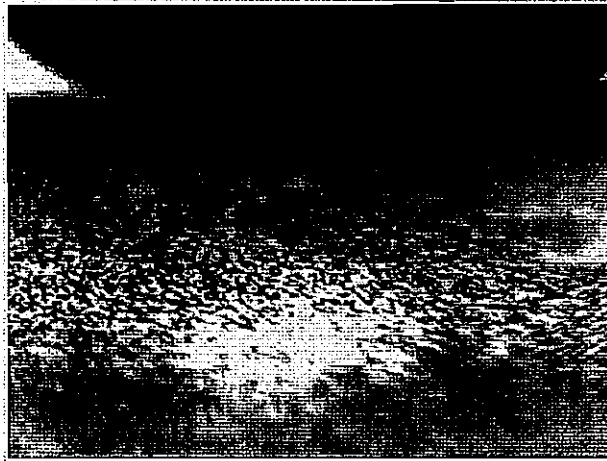
15. In the first video (Movie No. 1), the toothbrush, including the bristles, was submersed in water, above a surface containing a biofilm. The bristles were completely submersed because we discovered that if the bristles were only partly submerged, very many bubbles were generated obscuring the surface. Microbubbles, in the form of an ultrasound

contrast agent, were introduced into the water between the transducer waveguide and the surface containing the biofilm. The ultrasound waveguide was approximately 5 mm away from the surface containing the biofilm and the bristles did not touch the surface. The video shows that when the ultrasound is engaged, there is a rapid erosion of the biofilm from the surface. Shown below are still frames from the movie, showing the steady and rapid removal of the biofilm from the surface.

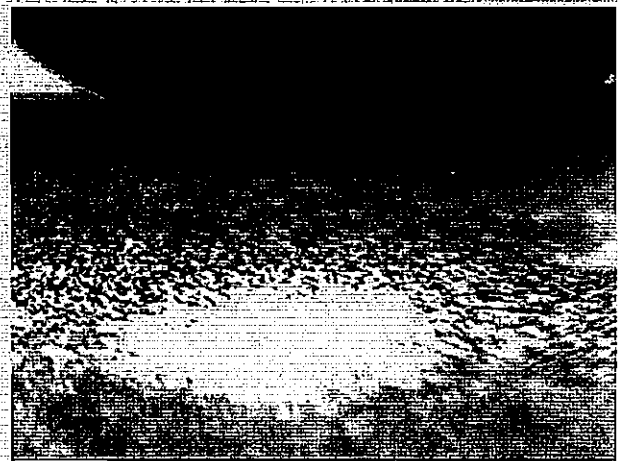
Frame 1



Frame 2



Frame 3



Frame 4

Fig. 1. Still frames (1 through 4) taken from Movie No. 1 showing the rapid and thorough removal of a biofilm from a surface by the action of the Ultreo toothbrush. The total time for this sequence was approximately 15 seconds.

16. There are two plausible mechanisms that could result in the biofilm erosion: (1) liquid streaming introduced by the oscillatory motion of the bristles, and (2) direct interaction of the bubbles with the surface. We performed a second series of experiments to determine if the erosion was the result of liquid streaming or the direct interaction of bubbles.

17. The second video (Movie No. 2) shows a close-up of the biofilm surface. Here, the magnification was such that the size of the individual bacteria colonies are about 50 microns in diameter (20 thousandths of an inch). As the video plays, ghost-like images can be seen moving around the surface. The images are gas bubbles. Their movement is slow and shaky because this movie was taken at approximately 1000 frames per second. Thus, there is only 1/1000 of a second between individual frames of the movie. If one were to look closely, one can see that one of the bubbles interacts with a bacteria colony and removes it from the surface. Still frames have been taken from this sequence to illustrate that phenomenon and are shown in Figure 2 below.

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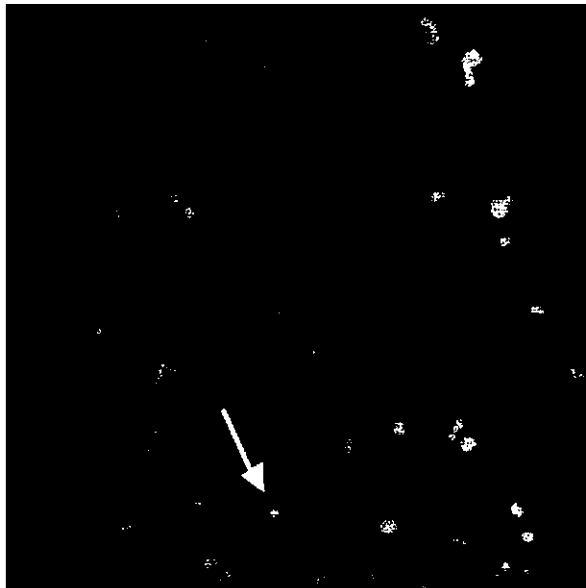
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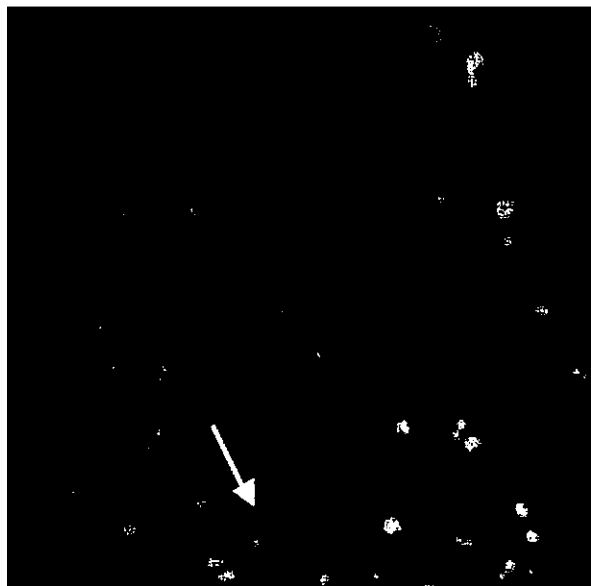
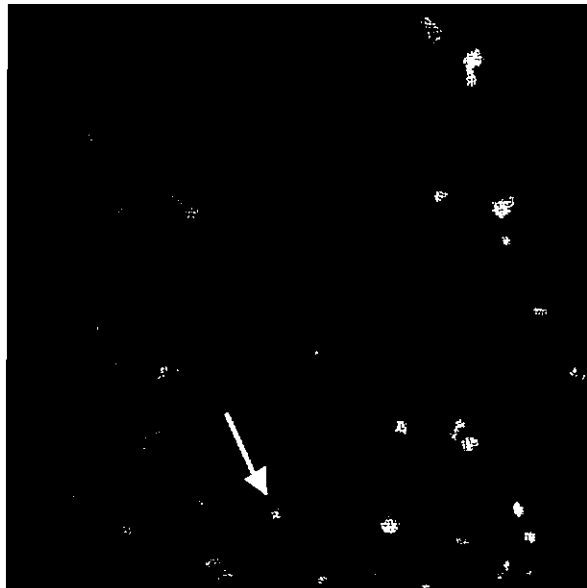
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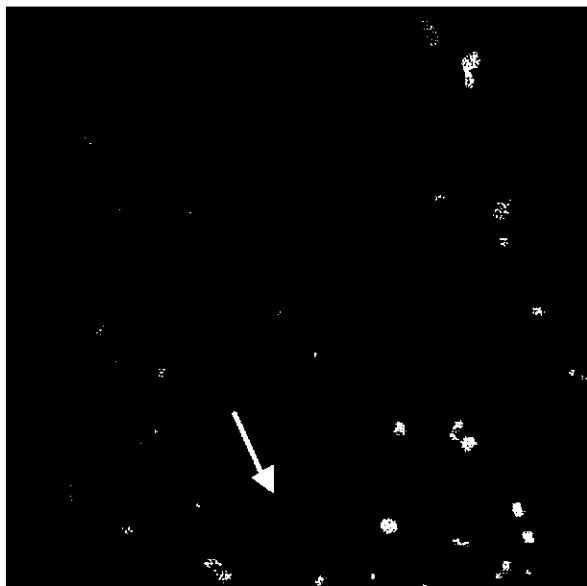
Frame 1



Frame 2



Frame 3



Frame 4

Fig. 2. Still frames taken from Movie No. 2. Note that a bacteria colony, indicated by the arrow, is overtaken by a moving bubble (the diffuse white image moving from 1 o'clock to 7 o'clock), and removed from the surface. Note also that no other colonies are removed.

18. Movie No. 2 and the still frames in Fig. 2 provide strong evidence that energetically oscillating bubbles are the principal mechanism that removes the surface biofilm.

19. Movie No. 3 shows a similar behavior to that of Movie No. 2 demonstrating that the observations shown in Movie No. 2 reflect the typical behavior of the Ultreo toothbrush. In Movie No. 3, the interaction of the bubble with the bacteria colonies is seen to be more dramatic, removing several of the colonies. Shown in Figure 3 below are still frames from this movie, showing again the direct interaction of the bubbles with the biofilm surface.

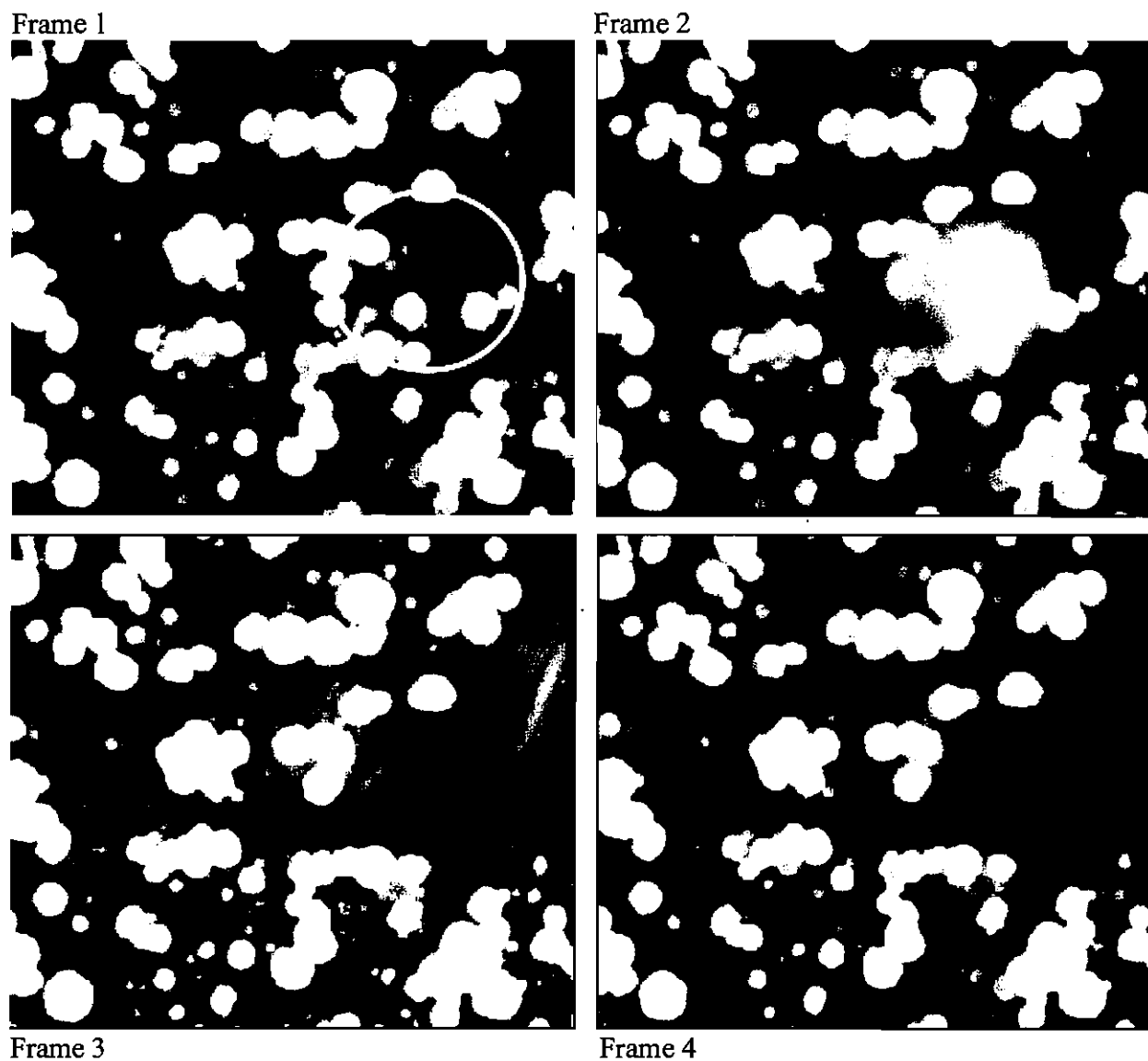


Fig. 3. Still frames from Movie No. 3 showing direct interaction of a bubble with the biofilm surface. Here, several bacteria colonies are removed from the surface by the energetic oscillations of the bubble. No other colonies are removed except those directly affected by the bubble.

20. These movies and still frames provide strong visual evidence that the mechanism that is responsible for removing the plaque bacteria from the surface of teeth by the Ultreo toothbrush is the direct interaction of bubbles with the bacteria colonies.

21. The conditions of the laboratory experiments depicted in the movies and the still frames are an appropriate analogue for the conditions that occur during toothbrushing with the Ultreo in the mouth. There are, of course, numerous differences between the conditions in the laboratory and the conditions in the mouth, including the viscosity of the fluid environment, the type of surfaces to be cleaned and the type of biofilm coating the surface. These parameters, however, are relatively minor in significance compared to the far more important parameters of the ultrasound energy produced by the Ultreo and the presence of bubbles in the fluid. For example, while the viscosity of the fluid environment could mitigate to some degree the propagation of ultrasound through the fluid, it will not substantially inhibit the effect. The differences in the parameters in the mouth compared to the lab may affect the *degree* of the ultrasonic cleaning effect, but they will not significantly denigrate the physical mechanism of cavitation that is producing that cleaning effect. That is because the important parameters of acoustic cavitation – namely, the ultrasonic energy produced by the Ultreo and the presence of bubbles in a fluid environment – are very powerful physical phenomena and are both present when the Ultreo toothbrush is used in the mouth.

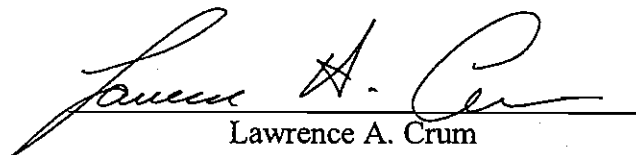
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22. In my opinion, based on a reasonable degree of professional certainty, the ultrasonic feature of the Ultreo toothbrush, at the very least, contributes to or assists in the plaque removal performance of the Ultreo in a person's mouth.

Date: December ²⁴11, 2007
Seattle, Washington



Lawrence A. Crum

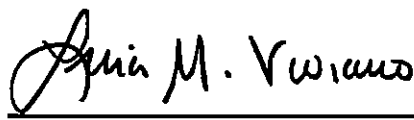
CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on December 12, 2007, I caused a copy of the foregoing **DIRECT EXAMINATION DECLARATION OF LAWRENCE A. CRUM** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

Laura W. Sawyer
JONES DAY
222 East 41st Street
New York, New York 10017

Attorneys for The Procter & Gamble Company

Dated: New York, New York
December 12, 2007



Lina M. Viviano